UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA

IN RE: Bair Hugger Forced Air Warming Products Liability Litigation	MDL No. 2666 (JNE/FLN)
This Document Relates to **ALL ACTIONS**	

MEMORANDUM IN SUPPORT OF DEFENDANTS' MOTION TO EXCLUDE PLAINTIFFS' GENERAL CAUSATION MEDICAL EXPERTS

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INTRODUCTION

The general causation opinions of Drs. Jonathan M. Samet, William Jarvis, and Michael J. Stonnington (hereinafter, "SJS") should be excluded from the MDL pursuant to Federal Rule of Evidence 702 and *Daubert v. Merrell Dow Pharms., Inc.*, 509 U.S. 579 (1993). They should also be excluded in the Ramsey County cases under Minnesota Rule of Evidence 702 and the *Frye-Mack* standard. SJS's shared opinion – that that the Bair Hugger system causes surgical site infections – is not based upon any scientifically convincing evidence, as is required by both federal and Minnesota law for general causation expert opinions.[1] *See Glastetter v. Novartis Pharms. Corp.*, 252 F.3d 986, 989-90 (8th Cir. 2001); *Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000).

Independent organizations, including most recently the FDA, that have considered the same studies cited by SJS, have ***uniformly*** rejected the inferences that SJS draw. Declaration of Benjamin W. Hulse ("Hulse Decl."), DX1, FDA Safety Alert, "Forced Air Thermal Regulating Systems: Healthcare Provider Letter – Information About Use" (Aug. 30, 2017) (reminding healthcare providers that forced air warming systems "have been demonstrated to result in less bleeding, faster recovery times, and ***decreased risk of infection for patients***" (emphasis added)). Indeed, these studies (virtually all of which were sponsored or orchestrated by Defendants' competitor, Scott Augustine) expressly disclaim any finding of causation.

[1] Minnesota law is addressed in the final section of this Memorandum.

Ultimately, SJS fall back on just one uncontrolled observational study to support their opinions that the Bair Hugger system does, in fact, increase the incidence of surgical infections: the 2011 McGovern study. On its face, the McGovern study disclaims any finding of causation. But the McGovern study does not – as its coauthor who performed the statistical analysis admitted under oath – even show an *association* between Bair Hugger use and increased infections, once even ***one*** of its several confounding factors (a mid-study change in the drug regimen used with patients) is accounted for. None of SJS can reliably base their opinions on such a weak foundation. *See Glastetter*, 252 F.3d at 990 (concurring with the district court that a scientific text that "ventured a hesitant conclusion" but "made clear that more research was needed before causation could be firmly established" was not "persuasive scientific evidence" of general causation).

In addition, Jarvis and Stonnington's opinions suffer from additional fundamental flaws that should lead to their exclusion. Jarvis's opinion and his endorsement of the McGovern study are diametrically opposed to the professional opinions and methodology he used while employed at the Centers for Disease Control. *Kumho Tire Co., Ltd. v. Carmichael*, 526 U.S. 137, 152 (1999) ("an expert must "employ in the courtroom the same level of intellectual rigor that characterizes the practice of an expert in the relevant field"). And Stonnington failed to provide any data to substantiate his personal observation from his own practice (an observation that he testified was critical to his ultimate general causation opinion) that infections declined after he discontinued use of the Bair Hugger system. His ultimate general causation opinion is simply *ipse dixit. See* Fed. R. Civ. P. 26(a)(2)(B).

Unlike Plaintiffs' other four experts, SJS are medical doctors. As doctors, they are the ***only*** experts on Plaintiffs' roster who are qualified to provide the necessary medical opinion that the Bair Hugger system caused Plaintiffs' injuries, including by first "ruling in" the Bair Hugger as a scientifically plausible cause. *See Glastetter*, 252 F.3d 986 at 989. If their opinions are excluded, Plaintiffs have no medical expert testimony upon which to base their theory of general causation and all their claims must fail, as explained in Defendants' concurrently filed summary judgment motion.

GOVERNING LEGAL PRINCIPLES

I. *DAUBERT* AND THE COURT'S DISCRETION TO EXCLUDE EXPERTS.

In *Daubert*, the Supreme Court addressed the admissibility of expert testimony and established "the exacting standards of reliability such evidence must meet." *Weisgram v. Marley Co.*, 528 U.S. 440, 455 (2000). "[T]rial courts must serve as gatekeepers to insure that proffered expert testimony is both relevant and reliable." *Wagner v. Hesston Corp.*, 450 F.3d 756, 758 (8th Cir. 2006) (internal quotation marks omitted); *see also Glastetter*, 252 F.3d at 988. The proponent of the testimony has the burden of proving the testimony is admissible. *See, e.g., Polski v. Quigley Corp.*, 538 F.3d 836, 841 (8th Cir. 2008).

First, the proponent must establish that the witness has the necessary expertise, in the form of "knowledge, skill, experience, training, or education," Fed. R. Evid. 702, to render an opinion on the issue addressed by the proposed testimony. *See Wheeling Pitt. Steel Corp. v. Beelman River Terminals, Inc.*, 254 F.3d 706, 715 (8th Cir. 2001).

Second, the proponent must establish that the expert's testimony is "reliable" – *i.e.*, that the testimony is "ground[ed] in the methods and procedures of science," as opposed to the expert's "subjective belief or unsupported speculation." *Daubert*, 509 U.S. at 589-90 (quotation marks omitted); Fed. R. Evid. 702 (testimony must be "based upon sufficient facts or data" and "the product of reliable principles and methods" and the expert witness must have "applied the principles and methods reliably to the facts of the case"). "Failure to show the reliability of each step in an expert's methodology is fatal under *Daubert*." *In re Baycol Prods. Litig.*, 532 F. Supp. 2d 1029, 1042 (D. Minn. 2007).

Third, the proponent must establish that the testimony "will help the trier of fact" in understanding issues relevant to the case, Fed. R. Evid. 702, meaning that the testimony must have "a valid scientific connection" to—*i.e.*, must "fit"—the pertinent inquiry in the lawsuit. *Daubert*, 509 U.S. at 591-92.

The decision to exclude an expert's testimony is, of course, committed to the discretion of the district court. *Glastetter*, 252 F.3d at 989.

II. GENERAL CAUSATION IN MEDICAL INJURY CASES AND THE REQUIREMENT OF SCIENTIFICALLY COMPELLING EVIDENCE.

The cause of medical injuries "requiring surgical intervention or other highly scientific technique for diagnosis . . . is not within the realm of lay understanding and must be established through expert testimony." *Turner v. Iowa Fire Equip. Co.*, 229 F.3d 1202, 1210 (8th Cir. 2000) (affirming summary judgment for defendant because plaintiff did not proffer medical expert testimony concerning the cause of her "sophisticated"

injuries). The surgical infections allegedly suffered by Plaintiffs here are indisputably the sort of injury that requires expert causation testimony.

As discussed below, three central legal principles govern this Court's evaluation of SJS's general causation opinions. ***First***, in medical injury cases, general causation expert opinions must be based upon "scientifically convincing evidence" that "demonstrates to an acceptable degree of medical certainty" that the defendant's product causes the types of injuries alleged by the plaintiffs. ***Second,*** general causation experts cannot draw conclusions from scientific articles and publications that the authors did not. As the Fifth Circuit has said, "[i]t is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation has been proved." *Huss v. Gayden*, 571 F.3d 442, 459 (5th Cir. 2009). And ***third***, to the extent that general causation experts rely on epidemiological studies, they must account for background risk – that is, the risk of the alleged type of injury in the general population, when the defendant's product has not been used. *See McClain v. Metabolife Int'l, Inc.*, 401 F.3d 1233, 1247-48 (11th Cir. 2005).

A. Eighth Circuit Law Requires That Plaintiffs' Experts Base Their General Causation Opinions on "Scientifically Convincing Evidence."

The Court has bifurcated expert proceedings into general causation and specific causation phases. In the general causation phase, Plaintiffs have disclosed experts, including SJS, who attempt to "rule in" the Bair Hugger system as a scientifically plausible cause of the Plaintiffs' alleged injuries. In the specific causation phase, Plaintiffs must disclose experts who "rule out" other plausible causes of their surgical site

infections. *See Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, n.2 (8th Cir. 2014) ("[T]he experts 'rule in' the reasonable plausible causes of injury and then 'rule out' or eliminate them from least to more plausible until a most plausible cause emerges.").

The Eighth Circuit's decision in *Glastetter* controls this Court's gatekeeping evaluation of "rule in" opinions.[2] In *Glastetter*, the Eighth Circuit affirmed the district court's exclusion of the plaintiff's causation experts because they lacked a proper basis for "ruling in" Novartis's Parlodel drug as a scientifically plausible cause of intracerebral hemorrhage (ICH). While the experts had articulated a theory of causation (that Parlodel causes vasoconstriction, which in turn causes ICH) that "appears sound," the Court observed that their "major premise" that Parlodel causes ICH "remains unproven." 252 F.3d at 989. The court discussed the evidence relied upon by the plaintiff's experts piece by piece, and concluded that none of it was "***scientifically convincing evidence*** that Parlodel causes vasoconstriction." *Id.* (emphasis added). The Eighth Circuit agreed with the district court that the plaintiff's experts' evidence "does not demonstrate to ***an acceptable degree of medical certainty*** that Parlodel causes an ICH." *Id.* (emphasis added; citing *Daubert*, 509 U.S. at 590 n.9 ("In a case involving scientific evidence, evidentiary reliability will be based upon scientific validity.")).

The Eighth Circuit first evaluated the plaintiff's experts' reliance material piece by piece. The medical texts cited by the plaintiff's experts were either "largely grounded

[2] *Cf. Johnson v. Mead Johnson & Co., LLC*, 754 F.3d 557, 563 (8th Cir. 2014) (noting that, because the defendant challenged only the plaintiff's expert's "rule out" opinions, "we fail to see how *Glastetter* is particularly relevant to this case").

upon case reports," "reported Parlodel's propensity to cause diseases *other* than ICH," or "ventured a hesitant conclusion that Parlodel causes vasoconstriction, but the explanation made clear that more research was needed before causation could be established." *Glastetter*, 252 F.3d at 990. The Eighth Circuit concurred with the district court's finding that these texts "do not present persuasive scientific evidence that Parlodel causes vasoconstriction." *Id.*

The Eighth Circuit ultimately held that the experts' evidence (which also included animal studies, internal corporate documents, the FDA's rescission of its approval of Parlodel, and rechallenge/dechallenge events), considered both individually and in the aggregate, did not provide scientifically convincing evidence of general causation: "Viewed in isolation, Glastetter's different pieces of scientific evidence do not substantiate her experts' conclusion that Parlodel can cause ICHs. Likewise, we do not believe that the aggregate of this evidence presents a stronger scientific basis for Glastetter's supposition that Parlodel can cause ICHs." *Id.* at 992.

In sum, under *Glastetter*, a plaintiff's medical causation experts can "rule in" the defendant's product as a plausible cause of the plaintiff's injuries only by basing their opinions on scientifically convincing evidence. Where, as here, the medical causation experts do not perform their own research but instead rely on published studies, they cannot draw conclusions that the study authors did not themselves draw.

B. Experts May Not Base Their General Causation Opinions on Studies That Disclaimed Any Finding of Causation.

Glastetter's treatment of third-party medical texts has been echoed by other courts. In the often-repeated phrasing of the Fifth Circuit, "[i]t is axiomatic that causation testimony is inadmissible if an expert relies upon studies or publications, the authors of which were themselves unwilling to conclude that causation has been proved." *Huss v. Gayden*, 571 F.3d 442, 549 (5th Cir. 2009); *see also Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 145-46 (1997) (studies did not support experts' conclusion that PCB exposure caused cancer because the doctors who conducted the study were unwilling to draw that conclusion); *Happel v. Walmart Stores, Inc.*, 602 F.3d 820, 826 (7th Cir. 2010) ("To the extent that Dr. Hirsch does rely on medical literature to support his [causation] theory, the articles to which he cites stop short of reaching the same conclusion."); *McClain*, 401 F.3d at 1247-48 (studies did not authorize conclusion that combination of ephedrine and caffeine is dangerous because authors of studies indicated that causation was not proven); *Vargas v. Lee*, 317 F.3d 498, 501-02 (5th Cir. 2003) (two studies did not support conclusion that trauma causes fibromyalgia because authors of both studies determined that causation was not established); *Moore v. Ashland Chem., Inc.*, 151 F.3d 269, 278 (5th Cir. 1998) (en banc) (affirming trial court's exclusion of expert testimony because, among other reasons, the authors of a study relied upon by the expert "made it clear that their conclusions were speculative because of the limitations of the study"); *Newkirk v. ConAgra Foods, Inc.* 727 F. Supp. 2d 1006 (E.D. Wash. 2010) (excluding plaintiff's expert who drew conclusion that the authors of the study on which he relied "explicitly

stated was premature without additional data"), *aff'd*, 438 F. App'x 607 (9th Cir. 2011); *Amorgianos v. Nat'l R.R. Passenger Corp.*, 137 F. Supp. 2d 147, 187 (E.D.N.Y. 2001) ("Given that Means et al. declined to attribute the [peripheral nervous system] effects they observed to xylene simply because it was the most prevalent solvent in the lacquer, it is highly questionable how Dr. Rutchkic can reliably conclude from their work that xylene can cause [polyneuropathy]" and excluding expert's testimony."), *aff'd in relevant part*, 303 F.3d 256, 270 (2d Cir. 2002).

C. Consideration of Background Risk Is Critical to a General Causation Opinion Based Upon Epidemiology.

Finally, general causation expert opinions based upon epidemiology must consider background risk in the general population. Background risk "is the risk a plaintiff and other members of the general public have of suffering the disease or injury that plaintiff alleges *without* exposure to the drug or chemical [or here, the medical device] in question." *McClain*, 401 F.3d at 1243 (emphasis in original). "Because epidemiology aims to identify 'agents that are associated with an increased risk of disease,' Green, Reference Manual at 336, one must know the background prevalence of a disease before one can determine if exposure to an agent has increased the risk of that disease." *In re Denture Cream Prods. Liab. Litig.*, 795 F. Supp. 2d 1345, 1355 (S.D. Fla. 2011) (*citing* Michael D. Green et al., *Reference Manual on Scientific Evidence* 336 (Fed. Jud. Ctr. 2d ed. 2000)), *aff'd*, *Chapman v. Procter & Gamble Distributing, LLC*, 766 F.3d 1296, 1307 (11th Cir. 2014). Thus, "[a] reliable methodology should take into account the

background risk." *McClain*, 401 F.3d at 1243. In other words, background risk is not a plaintiff- or case-specific consideration. It applies across all plaintiffs and all cases.

This requirement has been extended to medical device litigation. *Kilpatrick v. Breg*, No. 08-10052-CIV, 2009 WL 2058384, at *8 (11th Cir. June 25, 2009) (excluding expert's general causation opinion in pain pump case for not explaining his methodology for calculating background risk). Likewise, it should apply to this litigation because there is no dispute that post-surgical site infections regularly occurred before the Bair Hugger system and forced air warming were ever used in surgeries.

Moreover, while the case authority requiring consideration of background risk has emerged outside the Eighth Circuit, it is fully consistent with Federal Rules of Evidence and Eighth Circuit law, which require experts to account for obvious alternative explanations for the plaintiff's injury. *See* Fed. R. Evid. 702 advisory committee notes (2000 amends.) (in determining the reliability of an expert's opinion, courts consider "[w]hether the expert has adequately accounted for obvious alternative explanations"); *Redd v. DePuy Orthopaedics, Inc.*, No. 16-3428, 2017 WL 2859536, at *3 (8th Cir. July 5, 2017).

SUMMARY OF PLAINTIFFS' MEDICAL EXPERTS' OPINIONS

SJS all opine that the Bair Hugger system increases the risk of surgical site infections in orthopedic surgeries. Samet is the only one of the three who attempts to quantify the increased risk, and he relies exclusively on the McGovern study, an uncontrolled observational study with major acknowledged confounding variables, for the quantification. The other two, Drs. Jarvis and Stonnington, conclude that the Bair

Hugger system increases risk, but do not quantify the increase. They also cite the McGovern study.

A. Samet

Dr. Samet is a medical doctor with a master's degree in epidemiology. DX2, Samet Rpt. at 1.[3] His research focuses on the health consequences of inhaled agents, including tobacco and radon. *Id.* at 2. In the world of litigation, he is known for his work as the plaintiffs' expert in the tobacco litigation. In this litigation, Samet opines that the Bair Hugger system increases the risk of surgical infections. *Id.* at 16-17. He relies exclusively on the McGovern study to support his quantification of that risk. He concedes that, without the McGovern study's finding of a 3.8 odds ratio, he "would have no basis for describing the quantitative magnitude of the risk." DX3, Samet Dep. at 283:16-20 ("Q. So you wouldn't be offering that – that opinion; correct? A. I wouldn't have the basis for doing so.").

Though not a biomedical engineer, Samet also opines that the Bair Hugger system provides a "causal mechanism" for surgical site infections. Put more simply, his opinion is that a chain of events *could* occur whereby the Bair Hugger system *could* cause a surgical site infection. For this opinion, he cites non-epidemiological third-party studies (which are the product of Augustine's publication factory, as detailed in Defendants' motion to exclude Plaintiffs' engineering experts) and the modeling performed by fellow Plaintiffs' expert Said Elghobashi. DX2, Samet Rpt. at 13-15. These unreliable

[3] All citations to "DX" in this Memorandum are exhibits to the concurrently filed Declaration of Benjamin W. Hulse.

Augustine-generated studies and Elghobashi's model are addressed in the concurrently filed Motion to Exclude the Opinions and Testimony of Plaintiffs' Engineering Experts.

B. Jarvis

Dr. Jarvis is a medical doctor who claims experience in infectious disease, healthcare epidemiology, and infection control. He formerly worked at the CDC with a focus on infectious diseases associated with healthcare. DX4, Jarvis Rpt. at 1. Jarvis reviews certain medical literature and concludes "that the Bair Hugger FAWs, to a reasonable degree of medical certainty, cause or substantially contribute to SSIs [surgical site infections] in PJA [prosthetic joint arthroplasty] patients." *Id.* at 25. Jarvis does not attempt to calculate a risk ratio or otherwise quantify the additional risk of infection caused by use of the Bair Hugger system. The only study he cites that does calculate a risk ratio is, once again, McGovern. DX5, Jarvis Dep. at 190:15-19 ("Q. Was there any other study [other than McGovern] that you referenced in your report that purported to show a relative risk of Bair Hugger versus some other warming modality in terms of joint infections? A. No. That was – that was the solid one."). Like Samet, Jarvis relies on the modeling of Elghobashi and third-party publications to support his other opinion that the Bair Hugger system provides a causal mechanism for infections.

C. Stonnington

Dr. Stonnington is an orthopedic surgeon. He is not trained in epidemiology or biomedical engineering. He conducted a review of literature provided to him by Plaintiffs' counsel. DX6, Stonnington Rpt. at 4-7. Stonnington concedes that McGovern is inconclusive. DX7, Stonnington Dep. at 24:18-22, 25:1-19 (agreeing that McGovern's

findings cannot be considered conclusive and describing McGovern as a "tree in the forest" that "cannot be considered authoritative on its own"). He likewise concedes that none of the other studies he reviewed are authoritative. *Id.* at 25:1-19, 26:24–27:8 (testifying that the studies he cites are "part of the forest but you cannot look at all the conglomeration of studies as the whole forest" and that the studies are "very important trees" but none is "authoritative").

So how does he make a "forest" out of these non-authoritative, inconclusive "trees"? Unlike Samet and Jarvis, Stonnington does not rely upon Elghobashi's modeling. Instead, Stonnington reaches his opinion by drawing on his own personal observations from his orthopedic practice, where he asserts that he saw a decline in infection rates after he discontinued use of the Bair Hugger system. DX6, Stonnington Rpt. at 6 ("Based on the data generated by recent studies and my own observations, the most likely cause of these increased infection rates is the use of Bair Hugger warming devices . . . ."; DX7, Stonnington Dep. at 269:13–270:6 ("Yes, I reviewed journal articles, I looked at my own practice, I reviewed my own patient outcomes."). But Stonnington did not disclose any data that might support – or disprove – his personal, subjective observations from his medical practice. He concedes that he has not done an actual study. *Id*. at 39:12–40:14, 96:14-16.

ARGUMENT

I. THE McGOVERN STUDY IS NOT SCIENTIFICALLY CONVINCING EVIDENCE OF GENERAL CAUSATION.

The McGovern study is the *only* epidemiological study cited by SJS in their reports, and the only basis any of them offers for quantifying the alleged increased infection risk from use of the Bair Hugger system. Without an epidemiologic basis for quantifying any purported increase risk from the Bair Hugger, Plaintiffs' experts are left with nothing more than the hypothetical, speculative, and inconclusive "evidence" from the Augustine-orchestrated mechanistic experiments and Elghobashi's modeling.

The McGovern study looked at infection rates at Wansbeck Hospital in Northumbria, England, during a period when the Bair Hugger system was in use versus a period when Augustine's HotDog was in use. It was an observational study, meaning that it was not blinded and controlled like a clinical study. DX12, Albrecht Dep. at 132:3–134:10. *See In re Prempro Prods. Liab. Litig.*, 738 F. Supp. 2d 887, 891 (E.D. Ark. 2010) ("Because this procedure lacks controls, observational studies are more susceptible to bias and other confounding factors, and so are less reliable than clinical studies, which are often referred to as the 'gold standard.'").

The data analyzed by the authors was taken from a 27-month period from July 2008 to December 2010, when surgical site infections at the hospital were seemingly out of control and had been identified as a "high outlier" in the English National Health System. DX8, Reed Dep. at 65:18–66:23; DX9, Borak Rpt. at 11. Infection rates were also highly variable, indicating that outbreaks of infection were occurring. DX10,

Holford Rpt. at 4 (concluding from infection rates that "there is strong evidence that the rates were highly variable" during the time of the McGovern study and that "there were actually two separate outbreaks of infection").

McGovern co-author Michael Reed testified that the initial objective of the study was different. The study initially consisted of an experiment, funded by Augustine, to determine whether the Bair Hugger system had a greater effect on operating room airflow than Augustine's HotDog. There was no difference. DX8, Reed Dep. at 25:14-25. With that negative result, the authors decided to look at infection rates in the Bair Hugger and HotDog periods. This comparison was, in Reed's words, "more opportunistic." *Id.* at 25:17-21.

For the following reasons, the McGovern study does not provide scientifically convincing evidence to support the opinions of SJS.

A. The McGovern Study Expressly Disclaims Any Finding of Causation.

It is well established that Plaintiffs' experts cannot rely on a study to support conclusions that the study authors were unwilling to reach. *See Glastetter*, 252 F.3d at 990; *Huss*, 571 F.3d at 459; *Joiner*, 522 U.S. at 145. Yet that is precisely what SJS (or at least Samet and Jarvis – Stonnington is more circumspect) do in their discussion of McGovern.

On its face, the McGovern study does not support SJS's conclusion. McGovern and his coauthors expressly disclaimed any conclusion that the Bair Hugger system causes surgical site infections: "This study does not establish a causal basis for this association." DX11, McGovern P.D. et al., "Forced-air warming and ultra-clean

ventilation do not mix." 93-B(ll) *J. Bone & Joint Surg.-Br.* 1537, 1543 (2011). Co-author Michael Reed was blunt in his deposition. Asked why the authors said this, Reed replied: "Because it doesn't. It doesn't establish causation, our paper." DX8, Reed Dep. at 227:24–228:14. Another co-author, longtime Augustine employee and collaborator Mark Albrecht (who was responsible for the statistical analysis in the study), agreed: "The study does not establish a causal basis and that's – there's a lot of confounding [mistranscribed as 'compounding'] factors that could be at play." DX12, Albrecht Dep. at 177:13–178:10. In a communication with another researcher, Albrecht admitted that he had admonished Augustine (apparently to no effect) not to overstate the study's findings: "This is one of those things where we can step close to the line, and we do have important information to present that clinicians should be aware of, but we also have to be careful that we do not state claims regarding proof of infection reduction. Unfortunately, Scott [Augustine] likes to say that he's convinced of such a relationship, even though I tell him it is unsupported and I do not agree. Well, that is the difference between research and marketing."[4] *Id.* at 343:8–345:9. That is also the difference between research and SJS's litigation opinions.

[4] In earlier days, Augustine himself conceded that there is no scientific proof that the Bair Hugger system causes surgical site infections. In an archived version of Augustine's "Frequently Asked Questions" webpage advertising the HotDog, Augustine admitted: "Is Augustine claiming that forced-air warming causes infections? Of course not . . . . To prove "cause" in a scientific sense would require a massive controlled, blinded study. No such study has been done . . . and may not even be possible." DX13, HotDog Patient Warming, "Refund Guarantee," previously available at http://www.hotdog-usa.com/guarantee.php (July 12, 2012).

B. When Admitted Confounders and Tabulation Errors Are Factored In, There Is Not Even Any Association.

Association is, of course, not equivalent to causation. *See Reference Manual on Scientific Evidence* at 336 (2d ed.) ("[I]t should be emphasized that *an association is not equivalent to causation.*" (emphasis in original).); *see also In re Lipitor (Ataorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig*, MDL No. 2:14-mn-02502-RMG, 2016 WL 8739552, at *10 (D.S.C. Dec. 29, 2016) (collecting cases). The McGovern study does not even demonstrate an association between Bair Hugger use and increased infection rates when acknowledged confounders are factored in.

The authors expressly acknowledge several confounding variables, included the fact that there was a period when different anti-thrombotic and prophylactic antibiotic drugs were being used with the two groups of patients.:

> Although the demographics were similar between the patient groups in terms of risk factors for infection, the data are observational and may be confounded by other infection control measures instituted by the hospital. For example, changes were made to the antibiotic and thromboprophylaxis protocols used during the study, although no infection control changes were made after February 2010.
>
> In addition, we were unable to consider all factors that have been associated with SSI, as the details of blood transfusion, obesity, incontinence and fitness for surgery, which have been identified elsewhere as important predictors for deep infection, were not sufficiently detailed in the medical record.

DX11, McGovern at 1543. Coauthor Albrecht likewise acknowledged that the "reduction in infections rates shown in the study [when the HotDog was being used] could be due to the adoption of conductive fabric ***or it could be due to outside factors***." DX12, Albrecht Dep. at 134:24–135:16 (emphasis added). These factors, Albrecht

admitted, "could be anything. Improvement in surgical practices, perhaps. There's an antibiotic switch that was occurring somewhere in the study's period. You could have a different group of physicians operating. These are all uncontrolled things that don't get caught with observational research." *Id.* at 134:17–135:1.

The changes in drug regimen are clearly important. Albrecht testified that, for the periods where the same drug regimen was used, the difference in infection rates between those warmed with the Bair Hugger system and those warmed with the HotDog "would not be significantly different." DX12, Albrecht Dep. at 200:9-20. *See Joiner*, 522 U.S. at 145 (affirming exclusion of epidemiological study where the increase in the incidence of cancer among workers exposed to PCS was not statistically significant). Albrecht admitted that, in retrospect, it "would have been nice" if the McGovern study had disclosed that the association disappeared when the change in drug regimen was accounted for. *Id.* at 203:4-8; *see also id*. at 216:2-22 ("Having you make me drill into it [the data] a little more clearly like that and not treat it [the change in drug regimen] as just a confounder that, we'll, it's there, so you can't truly trust this, you know, I would have dug in a little deeper and put an effect in the table, I think.").[5]

Theodore Holford, professor of public health and biostatics at Yale, reached the same conclusion Albrecht reached under cross-examination. Prof. Holford reanalyzed

[5] In Albrecht's words, the purpose of the McGovern study was to "get other people to looking at it" (that is, the question of an association between the Bair Hugger system and surgical site infections) rather than to actually answer that question. DX12, Albrecht Dep. at 223:18–224:9.

the underlying data for the McGovern study after controlling for the change in the antithrombotic regimen and found no statistically significant difference between the Bair Hugger system and the HotDog. DX10, Holford Rpt. at 5-6. He also performed a reanalysis that controlled for both antithrombotic and antibiotic regimens, and the infection rates in the two groups were "virtually identical." *Id.* at 6, 7. SJS offered no rebuttal to Albrecht and Holford's math. As Samet conceded, Holford "certainly did the calculations correctly." DX3, Samet Dep. at 126:3-7.

There also are significant, undisputed tabulation errors in the McGovern study. *See In re Viagra Prod. Liab. Litig.*, 658 F. Supp. 2d 936, 944-45 (D. Minn. 2009) (epidemiological study cited by plaintiff's expert was not reliable, despite being published and peer-reviewed, because plaintiffs failed to rebut miscodings and errors identified by defendants). In his expert report, Dr. Jonathan Borak, a clinical professor of epidemiology and public health at Yale, notes that one of the HotDog infections was tabulated as a Bair Hugger infection. DX9, Borak Rpt. at 17-19; DX10, Holford Rpt. at 2-3 & n.1. McGovern study co-author Reed conceded in his deposition that this occurred, and that he informed Augustine's employee Mark Albrecht of the issue, but that Albrecht did not correct the error. DX8, Reed Dep. at 42:23–44:9 ("[It is not the latest data they have got in there [the published study], and I don't know why that is."); *see also* DX10, Holford Rpt. at 3 n.1.

In his analysis of the data, Dr. Borak also found that infection data from an eight-month period was improperly excluded. He concludes: "If the study had not excluded the eligible SSI data from 10/07 to 6/08, then the study would have had no significant clinical

findings. Likewise, if the tabulation error described above had been corrected, then the study would have had no significant clinical findings."[6] DX9, Borak Rpt. at 19, 23. SJS do not dispute that when these tabulation errors are corrected, the association between the Bair Hugger system and infections disappears.

C. The McGovern Study Suffers from Other, Undisclosed Confounders.

While the McGovern study expressly identifies some confounding factors, there were a multitude of other confounders that were never disclosed to readers.

As co-author Reed testified, massive efforts were being undertaken by the Northumbria Healthcare NHS Trust (the operator of Wansbeck) at the time covered by the McGovern study to lower its infection rates. DX8, Reed dep. at 66:1–69:18. These efforts are described in a published article authored by the senior nurse and leader of the surgical site infection surveillance team at Wansbeck. *See* DX14, Gillson J. et al.,

[6] In his second deposition, Samet testified that a paper recently published by Augustine in a pay-to-publish Internet journal "corroborates" McGovern and bolsters its reliability. DX3, Samet Dep. at 227:8–228:2. Jarvis testified that he considers the Augustine publication "a piece of the puzzle like all the other references that I have in my report." DX5, Jarvis Dep. at 141:15-23. But one of the hospitals Augustine says he "studied" in his publication denied that it ever participated in any study. ECF No. 445, Aff. of Julie Hauser at ¶¶ 31-32 ("Ridgeview Medical Center did not participate in a study with Scott Augustine or any entity owned by Scott Augustine, including but not limited to, Augustine Temperature Management or Augustine BioMedical Design. The study never came to fruition between Ridgeview Medical Center and Scott Augustine, or any entity owned in whole or in part by him."). Dr. Borak explained in his deposition how Augustine cherrypicked his "data" to produce the result he wanted. DX21, Borak Dep. at 208:25–210:23. It is therefore no surprise that Plaintiffs disavowed Augustine's publication at the August 17, 2017 hearing before Judge Noel and represented that they did not intend to introduce it as evidence at trial. ECF No. 682 at 2. Samet's and Jarvis's reliance on Augustine's article, in the face of Plaintiffs' counsel's own disavowal, further supports the exclusion of their opinions.

"Implementing effective SSI Surveillance, *Infection Control* 71 (Oct. 2014) (hereinafter, "Gillon"). As Reed explained, "We made a number of changes. We made -- you know, we were looking everywhere we could, trying to get a marginal gain on reducing infection rates." DX8, Reed Dep. at 78:19–79:1. These changes included:

> (1) establishing a surgical site infection prevention control committee in December 2008 and undertaking fulltime surveillance of orthopedic infections;
>
> (2) hiring two full-time SSI surveillance nurses in early 2009;
>
> (3) repairing a malfunctioning laminar air flow system in the operating rooms;
>
> (4) color coding of surgical scrubs to restrict the number of personnel entering the operating rooms;
>
> (5) drawing a red line to demarcate the entrance to the operating room where only essential personnel were permitted;
>
> (6) introducing a policy barring operating room staff from wearing personal footwear and requiring washable operating room clogs that are never taken out of the operating room;
>
> (7) changing post-operative wound dressings;
>
> (8) undertaking a root-cause analysis of all infections;
>
> (9) screening all orthopedic implant patients for methicillin-susceptible staph. Aureus (MSSA) in addition to MRSA screening, and decolonizing patients testing positive for MSSA prior to surgery;
>
> (10) implementation of more effective preoperative skin-preparation;
>
> (11) implementation of prewarming of patients; prewarming, Reed conceded, "does have an impact on infection."

Id. at 68:3-24, 69:7-18, 78:3–79:2, 108:25–109:11, 112:18–113:22, 114:7-25, 115:11–119:6; DX14, Gillson at 72-73 & fig. 2. These are in addition to other changes made Northumbria's aggressive effort to address its out-of-control orthopedic infection rates.

DX14, Gillson *passim*.

Virtually all these changes were implemented during or at the end of the Bair Hugger-only period (July 2008 to February 2010), meaning that patients in the HotDog-only period benefitted from infection control protocols that had not been in place for the majority of patients in the Bair Hugger-only period. *See id.* fig. 2. Yet neither Samet, Jarvis, nor Stonnington ever considered these major undisclosed confounders in forming their opinions that the McGovern study is a reliable foundation for establishing general causation. This failure also renders their opinions inadmissible. *See* Michael D. Green, et al., "Reference Guide on Epidemiology," *Reference Manual on Scientific Evidence* 549, 598 (Fed. Jud. Ctr. 3rd ed. 2011) ("In assessing causation, researchers first look for alternative explanations for the association, such as bias or confounding factors . . . ."); *id.* at 612-13 (noting that the propriety of using epidemiology to infer causation depends upon evaluating whether confounding factors are the source of the association); *see also Joiner*, 522 U.S. at 146-47 (study that failed to control for other factors that may have caused plaintiff's cancer did not reliably support the expert's opinion).

D. The McGovern Study Does Not Account for Background Risk.

Finally, there is no dispute that the McGovern study does not account for background risk. *McClain*, 401 F.3d at 1243 (excluding epidemiology-based opinion that did not account for background risk). Surgical site infections have always occurred, with or without use of patient warming technology. They arise from the complex set of circumstances of a patient's surgery, involving bacteria that live on a patient's skin around the surgical site, bacteria carried by the blood and living in nearby internal organs,

bacteria on the surgical staff, and bacteria carried on contaminated surgical equipment. DX19, CDC Guideline at 103. Yet the McGovern co-authors calculate a risk ratio by comparing infection rates with the Bair Hugger system ***and with a different warming device***, Augustine's HotDog. Neither McGovern nor SJS compare Bair Hugger infection rates to infection rates without use of any patient warming technology. DX3, Samet Dep. at 101:13-20 ("Q. Well, there are – are there any data upon which you rely that compared Bair Hugger to nothing? A. The – the observational data that I examined was the McGovern study in my March 30 report. Q. And that compares one warming modality to another; right? A. That's correct.").

Indeed, the research looking at infection rates without warming versus infection rates with the Bair Hugger system has found a ***reduced*** rate of infection, as the FDA recently noted in a communication to healthcare providers. DX1, FDA Safety Alert; *see also* DX15, ECRI, "Forced-Air Warming and Surgical Site Infections: Our Review Finds Insufficient Evidence to Support Changes in Current Practice," Guidance Article 122, 123-24 (April 2013) (discussing Melling study, which found significantly lower SSI rates in Bair-Hugger-warmed patients than in nonwarmed patients). Thus, the McGovern study not only provides no reliable basis for "ruling in" the Bair Hugger system as the cause of surgical infections, but also no foundation for "ruling out" other scientifically supported causes of infections.

For all these reasons, the McGovern study is not scientifically convincing evidence that can support SJS's general causation opinions. *Glastetter*, 252 F.3d at 989.

II. THE MODELING AND NON-EPIDEMIOLOGICAL, EXPERIMENTAL STUDIES CITED BY SJS ARE NOT RELIABLE.

While *Glastetter* notes that epidemiological evidence is not absolutely necessary to support general causation expert opinions, it also makes clear that non-epidemiological evidence must still be sufficient to "demonstrate to an acceptable degree of medical certainty" that the defendant's product can cause the injuries alleged by the plaintiffs. 252 F. 3d at 989. The absence of human epidemiological studies "only heightens the need for [the plaintiff's expert] to present other forms of highly persuasive scientific evidence to lay a foundation for his expert opinions." *Kilpatrick*, 2009 WL 2058384 at *5. The modeling and non-epidemiological, experimental studies relied upon by SJS fall far short of that standard.

Elghobashi's modeling, which is relied upon by Jarvis and Samet to support their opinions that the Bair Hugger system provides a "causal mechanism" for surgical site infections, is unreliable for the reasons explained in the contemporaneously Motion to Exclude the Opinions and Testimony of Plaintiffs' Engineering Experts. The other third-party experimental studies cited by SJS are discussed at length in that motion and briefly here. These publications do not satisfy *Glastetter*'s standard for scientifically convincing evidence.

In *Glastetter*, the plaintiff's experts relied on medical texts suggesting that Parlodel acted as a vasoconstrictor. Only one "ventured a hesitant conclusion that Parlodel causes vasoconstriction, but the explanation made clear that more research was needed before causation can be firmly established." *Id.* at 990. Here, none of the various

journal articles cited by SJS ventures any conclusion – not even a "hesitant" one – that the Bair Hugger system causes surgical site infections. Indeed, time and again the articles they cite (like McGovern) expressly disclaim any such conclusion:

Publication	**Language Disclaiming Conclusion that Bair Hugger Warming Blanket Increases Risk**
Albrecht M, et al., Forced-air warming: a source of airborne contamination in the operating room? *Orthopedic Rev.* 2009; 1(2):e28	"[T]he present study **did not evaluate the link between forced air warming and surgical site infection rates** …"
Albrecht M., et al., Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. *Am J Infect Control* 2010; 39:321-28	"[O]ur findings **do not establish a direct link** between forced air warming and increased surgical site infection rates …"
Legg A., et al., Do forced air patient-warming devices disrupt unidirectional downward airflow? *J Bone & Joint Surg-Br.* 2012; 94-B:254-6	"Because of the nature of our experiment **we are unable to conclude that the use of the forced air warming device … would actually lead to an increased risk of surgical site infection**."
Dasari K.R., et al., Effect of forced air warming on the performance of operating theatre laminar flow ventilation. *Anaesthesia* 2012; 67:244-49	"Another limitation of our study is that **the definitive effects of this excess heat on clinical outcomes is presently unknown.**"
Legg A., et al., Forced-air patient warming blankets disrupt unidirectional airflow. *Bone Joint J.* 2013 Mar; 95-B(3):407-10	"**This study does not show that forced-air warming increases the risk of infection** …"
Reed M., et al., Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. AANA J. 2013 Aug; 81(4):275-80	"Last, we did not track hospital infections, **nor did we study the association between FAW [forced-air warming] contamination generation/emission and hospital infection rates** …"

Belani K., et al., Patient warming excess heat: The effects on orthopedic operating room ventilation performance. *Anesthesia &Analgesia* 2012 (prepublication on-line) 2013; 117(2):406-411	"Thus, we are **unsure of the exact degree of ventilation disruption that might occur** in a working OR during orthopedic surgery… **future research is warranted** to characterize the clinical conditions under which forced air warming excess heat results in ventilation disruption during surgery."

Moreover, as in *Glastetter*, this Court is entitled to "regard [plaintiff's] experts claims with some suspicion" because leading authorities on the safety of medical devices, including most recently the FDA, do not reach the conclusions that plaintiff's experts reach. 252 F.3d at 990. For example:

(1) An independent review published by the Association of periOperative Registered Nurses (AORN) in 2013 concluded: "Our review uncovered no conclusive evidence that the use of forced-air warmers increases the risk of SSI . . . . The evidence also does not support the concern that use of a forced-air warmer may cause an increase in bacteria near or on the patient or cause unwanted airflow disturbances. These findings confirm the AORN recommendations that forced-air warming is an effective way to prevent unplanned perioperative hypothermia." DX16, Kellam M.D., et al., "Forced-air warming devices and the risk of surgical site infection," 98.4 *AORN Journal* 353, 365-66 (2013).

(2) Also in 2013, the ECRI Institute, a widely respected nonprofit organization that advises more than 5,000 healthcare organizations, reviewed over 180 studies, including McGovern. ECRI concluded: "we do not believe that the currently available

evidence justifies discontinuing the use of FAW [forced air warming] during surgery." DX15, ECRI Guidance Article at 122.

(3) Another independent review by Sikka and Prielipp in the *Journal of Bone & Joint Surgery* in 2014 concluded that "the literature appears to indicate that forced air warming can impact laminar flow under certain very specific conditions, but any actual clinical impact on surgical site infections must be considered unproven at this time." DX17, Sikka R.S., et al., "Forced Air Warming Devices in Orthopaedics: A Focused Review of the Literature," 96-A:24 *J. Bone & Joint Surgery* e200 (2014).

(4) The 2013 Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection, which involved more than 400 experts in musculoskeletal infection from 52 countries, reached a "strong consensus" as follows: "We recognize the theoretical risk posed by FAW [forced air warming] blankets and that no studies have shown an increase in SSI [surgical site infections] related to the use of these devices. We recommend further study but no change to current practice." DX18, Proceedings of the International Consensus Meeting on Periprosthetic Joint Infection at 5 (2013). Eighty-nine percent of delegates voted in support of the statement while only five percent voted against and six percent abstained.[7] *Id.*

[7] See also DX22, Duke Infection Control Outreach Network, "HotDogs, Bair Huggers, and Lawsuits, Oh My! A brief review of the controversy surrounding perioperative warming methods," *Infection Prevention News* (Nov. 2015) (finding that "no adequately powered, properly controlled, statistically significant, reproducible study has been published that demonstrates an increased risk of SSI due to the use of FAW warming devices," criticizing the McGovern study, and noting that "no studies performed by independent investigators" had corroborated its findings); DX23, Allen M.W. et al.,

(5) Last month, the FDA issued a letter to healthcare providers regarding forced air warming devices, after it became aware that "some health care providers and patients may be avoiding the use of forced air thermal regulating systems during surgical procedures due to concerns of a potential increased risk of surgical site infection (e.g., following joint replacement surgery)." DX1, FDA Safety Alert. The FDA conducted "a thorough review of available data," but "has been unable to identify a consistently reported association between the use of forced air thermal regulating systems and surgical site infection." *Id.* The agency reiterated the benefits of forced air warming and made clear that it "continues to recommend the use of thermoregulating devices (including forced air thermal regulating systems [of which the Bair Hugger is the most widely used]) for surgical procedures when clinically warranted." *Id.*

In sum, medical professionals and medical device regulators who have reviewed the evidence outside the context of litigation do not reach the same conclusions that SJS have reached as litigation experts. *See Kumho Tire*, 526 U.S. at 152; *Norris v. Baxter Healthcare Corp.*, 379 F.3d 878, 884 (10th Cir. 2005) (experts' opinions were "not medically or scientifically valid" when experts "completely ignored or discounted without explanation" studies contradicting their conclusions").

Of course, "[a] court may conclude that there is simply too great an analytical gap between the data and the opinion offered." *Joiner*, 522 U.S. at 146. Here, there is more

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"Normothermia in Arthroplasty," 32:7 *J. Arthroplasty* 2307, 2312 (July 2017) ("Despite recent controversy about forced air warming devices, the literature does not support to an increased risk for infection with such technologies.").

than an "analytical gap" between the publications relied upon by SJS and the opinions they have offered – there is a chasm.

III. JARVIS DOES NOT APPLY THE SAME RIGOR TO HIS LITIGATION OPINIONS THAT HE APPLIES IN HIS PROFESSIONAL RESEARCH.

One of the relevant factors in determining the admissibility of expert testimony is "[w]hether the expert 'is being as careful as he would be in his regular professional work outside his paid litigation consulting.'" Fed. R. Evid. 702, Advisory Committee Notes, factor 4 (2000), *quoting Sheehan v. Daily Racing Form, Inc.*, 104 F.3d 940, 942 (7th Cir. 1997). Jarvis's litigation opinion and his endorsement of the McGovern study stand in stark contrast to his professional opinions and methodology while he was at the CDC.

A. Jarvis's Litigation Opinion That Most SSIs Are Caused by Exogenous Sources Is the Exact Opposite of His Professional Opinion at the CDC.

Jarvis was employed by the CDC from 1980 to 2003. In 1999, he was one of the authors of the CDC's seminal Surgical Site Infection Prevention Guideline. DX19, CDC Guideline at 103. In that document, Jarvis noted: "For most SSIs, the source of pathogens is the endogenous flora of the patient's skin, mucous membranes, or hollow viscera." *Id.* Fast forward to 2017. Jarvis now takes a diametrically opposite position, opining that "[e]xogenous sources [that is, sources originating outside the human body] account for the majority of SSIs." DX4, Jarvis Rpt. at 5.

In his deposition, Jarvis could not identify any published literature in the years between his 1999 CDC SSI prevention guidelines and his 2017 expert opinion in this matter that would justify the change in conclusion as to the source of the majority of surgical infections. DX5, Jarvis Dep. at 152:15-167:18. Struggling to justify his 180-

degree change in position as to the source of most SSIs, Jarvis purported to rely on his "personal analysis as well as experience at CDC investigating outbreaks for 17 years." *Id.* at 163:17-23.

The obvious problem with that explanation is that ***he already had*** those 17 years of experience at the CDC when he co-authored the Surgical Site Infection Prevention Guideline. In 1999, he applied what he described as the "CDC gold standard methodology" in drafting the SSI prevention guidelines. *Id.* at 164:10-25. Applying that "gold standard methodology" and writing to provide definitive guidance to health care providers on how best to prevent surgical site infections, he concluded that the majority of SSIs were caused by endogenous bacteria from the patients themselves. This, clearly, is the fruit of his "regular professional work," arrived at by employing the "level of intellectual rigor that characterizes the practice of an expert" in his field. *Kumho Tire*, 526 U.S. at 152.

Now, as a litigation expert, he proffers an opinion that is the exact opposite of what he had previously concluded in his "regular professional work" for the CDC. Given the opportunity to articulate what additional information he had in the intervening years that caused him to change his opinion so dramatically, he offered nothing new: just the experience he *already had* at the time he co-authored the CDC guidelines. It would be difficult to find a clearer example of an expert failing to employ the same level of intellectual rigor in the courtroom as he had applied in his professional career.

B. Jarvis Would Never Have Relied on a Flawed Study Like McGovern In His Professional Work at the CDC.

As noted above, Jarvis opines in this litigation that the McGovern study is a well conducted study using valid methodology such that he can rely—and rely heavily—on its findings. When Jarvis worked for the CDC, however, he employed a rather different methodology to examine a similar issue.

In 1990, Jarvis participated in an investigation into a large outbreak of infections following knee replacement surgery. This resulted in a published paper. DX20, Gordon, Jarvis, et al., "Risk Factors for Wound Infections After Total Knee Arthroplasty," 131:5 *Am. J. Epidemiology* 905 (1990). The investigation looked at 20 infections over just under four years, 18 of which were deep joint infections. DX5, Jarvis Dep. at 205:2–206:19. The CDC had been called in to investigate this unusual rate of infections by the hospital epidemiologist, who suspected that they were clustered around one surgeon. *Id.* at 209:7–210:1.

Because Jarvis and his CDC colleagues were aware that finding a specific surgeon responsible for the high rate of infection "would have a devastating impact" on that surgeon's career, they went "to the Nth degree looking at everything that could potentially—and even things that might not potentially—be associated with infection to make sure we were as solid as possible." *Id.* at 230:24-232:18. They examined records, conducted interviews, and compiled data on, among other things, the type of knee prosthesis implanted, whether it was fixed with cement or cementless, the number of personnel in the OR during surgery, the presence of assisting surgeons, whether there

were intraoperative irrigations, the duration of post-operative wound drains, the use of antimicrobial prophylaxis, the timing of the first dose of antimicrobial prophylaxis relative to skin incision, the total duration of the operation, the use of an intraoperative limb tourniquet, preoperative shaving, identity of the surgeon, use of a continuous passive motor machine after surgery, duration of post-operative fever, duration of antimicrobial exposure or administration, the time between surgery and documentation of infection, the wound culture results, and the time between initial procedure and first re-operation. *Id.* at 215:11–223:21, DX20, Gordon, Jarvis et al. Each of these factors was examined because each factor could potentially have an impact on the deep joint infection rate. DX5, Jarvis Dep. at 223:16-21.

Having gathered extensive information on multiple possible factors that could have impacted infection rates, Jarvis and colleagues then did a series of multivariate analyses to isolate any factors that were having a significant impact. *Id.* at 227:15–228:12. Through this process, they identified two significant factors in addition to the particular surgeon: the patient's ASA score (a measure of the patient's fitness for surgery) and use of the continuous passive motion machine. *Id.* at 228:14–229:1.

The thorough epidemiological study undertaken by Jarvis and his colleagues to investigate joint infections in Tennessee stands in stark contrast to the McGovern study relied upon by Jarvis here. There is no dispute that the McGovern study failed to consider any of the detailed factors considered by Jarvis when he was at the CDC. Nor did the McGovern study analyze the factors Jarvis and his colleagues considered using the multivariate statistical technique (which allows for comparison of multiple factors).

Instead, McGovern looked at a *uni*variate analysis: simply comparing infections in the Bair Hugger period to infections in the HotDog period. *Id.* at 216:8-16. No other factors were considered. The McGovern study did not even consider patient fitness for surgery, one of the unexpectedly significant factors in the Jarvis/CDC study. DX11, McGovern at 1543 (stating that "we were unable to consider . . . fitness for surgery").

Jarvis knows the right way to conduct an epidemiologic investigation into joint infections. He did it when he was at the CDC. Yet now, as a litigation expert, he has no trouble relying on a study that falls far short of the type of rigorous study he conducted when the results could potentially have a "devastating impact" on the career of a single surgeon. The contrast between his professional rigor at the CDC and what he is willing to do now as a litigation expert underscores the significance of this *Daubert* factor.

IV. STONNINGTON'S UNSUPPORTED PERSONAL OBSERVATIONS FROM HIS OWN MEDICAL PRACTICE ARE UNRELIABLE.

Stonnington's opinions should be excluded for the additional reason that they rely on top of the flimsiest of foundations: his *ipse dixit* based upon his own purported personal observations.

Stonnington has not disclosed any data whatsoever on the infection rates in his practice during and after discontinuation of Bair Hugger use. *See* Fed. R. Civ. P. 26(a)(2)(B) (expert must disclose "the facts or data considered by the witness in forming them); *Daubert*, 509 U.S. at 593 (absence of testing supporting expert's opinion is "key" factor weighing against admission); *Glastetter*, 252 F.3d at 989 (excluding expert's "unproven" hypothesis); *Solheim Farms, Inc. v. CNH Am., LLC*, 503 F. Supp. 2d 1146,

1150-51 (D. Minn. 2007) (excluding expert who "did not perform any testing to verify his theory"; [b]oth *Daubert* and *Kumho* make it clear that the day of the expert, who merely opines, and does so on the basis of vague notions of experience is over"). Casting further doubt on Stonnington's empirical assertions, he has never informed a patient that the Bair Hugger system caused the patient's infection, and never reported to the FDA any concern about the Bair Hugger warming system possibly causing his patients' surgical site infections. DX7, Stonnington Dep. at 95:12-16, 317:23–318:3.

In the most generous possible light, Stonnington's anecdotal report from his own practice is no better than the case reports that were found to be unreliable in *Glastetter*. *See Glastetter*, 252 F.3d at 989-90 (holding that case reports were not "scientifically valid proof of causation"); *Willert v. Ortho Pharm Corp.*, 995 F. Supp. 979, 981 (D. Minn. 1998) ("case reports are not reliable scientific evidence of causation, because they simply describe reported phenomena without comparison to the rate at which the phenomena occur in the general population or in a defined control group; do not isolate and exclude potentially alternative causes; and do not investigate or explain the mechanism of causation"). Indeed, they are even less reliable because Stonnington has not actually reported any of his patients' alleged infections.

At bottom, Stonnington's opinion is simply *ipse dixit*. Under *Joiner*, such opinions are inadmissible: "Even when an expert is extrapolating from personal experience as a practitioner rather than from reviewing research undertaken by others, 'nothing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence which is connected to existing data only by the *ipse dixit* of the

expert.'" *Estate of LeBlanc v. Chevron USA, Inc.*, 396 Fed. Appx. 94, 100 (5th Cir. 2010), *quoting Joiner*, 522 U.S. at 146. And under *Glastetter*, Stonnington's personal musings are not "scientifically convincing evidence" sufficient to support his general causation opinion.

V. PLAINTIFFS' MEDICAL EXPERTS' OPINIONS ARE ALSO INADMISSIBLE UNDER MINNESOTA STATE LAW.

SJS's opinions also should be excluded under Minnesota law because Plaintiffs' experts' general causation opinions do not satisfy the *Frye-Mack* standard, as codified in Minnesota Rule of Evidence 702. As already discussed, Plaintiffs' experts do not employ reliable principles and methodology, which is the first requirement of *Frye-Mack*. *See Goeb v. Tharaldson*, 615 N.W.2d 800, 814 (Minn. 2000). In addition, under Minnesota law, a scientific theory is not admissible unless the proponent demonstrates that it is generally accepted in the applicable medical or scientific community. *See id.* ("[W]hen novel scientific evidence is offered, the district court must determine whether it is generally accepted in the relevant scientific community."); *McDonough v. Allina Health Sys.*, 685 N.W.2d 688, 696 (Minn. Ct. App. 2004) (affirming exclusion of expert's general causation theory that was not generally accepted). The general causation opinions of SJS are not generally accepted – far from it. As explained above, their opinions go far beyond the conclusions of the studies they reply upon, and are contrary to the conclusions of all respected independent authorities who have looked at the issue.

CONCLUSION

The general-causation opinions of Plaintiffs' medical experts are not supported by scientifically convincing evidence and do not demonstrate an acceptable degree of medical certainty that the Bair Hugger system can cause surgical site infections. As such, their opinions should be excluded from the MDL under Fed. R. Evid. 702 and *Daubert* and from Ramsey County cases under Minn. R. Evid. 702 and the *Frye-Mack* standard. Their opinions also should be excluded under Minnesota law because they are entirely contrary to the consensus viewpoint of independent medical authorities and the FDA.

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Respectfully submitted,

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